DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#16

MAR 24 1989

Re: Optiray
Docket No. 89E-0055

The Honorable Donald J. Quigg
Assistant Secretary and Commissioner
of Patents and Trademarks
Washington, DC 20231

Dear Commissioner Quigg:

This is in regard to the application for patent term extension for U.S. Patent No. 4,396,598 filed by Mallinckrodt, Inc. under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Optiray, the human drug product claimed by the patent.

The total length of the review period for Optiray is 1,075 days. Of this time, 521 days occurred during the testing phase, and 554 days occurred during the approval phase. The periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 22, 1986.

   FDA has verified the applicant's claim that the investigational new drug application (IND) for Optiray became effective on January 22, 1986.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: June 26, 1987.

   The applicant claims that the new drug application for Optiray (NDA 19-710) was initially submitted on June 25, 1987. However, FDA records indicate that the application was not received until June 26, 1987.

3. The date the application was approved: December 30, 1988.

FDA has verified the applicant's claim that NDA 19-710 was approved on December 30, 1988.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: George R. Pepper
Bernard, Rothwell and Brown
1700 K Street, NW
Washington, DC 20006